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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,955	03/24/1999	MASAKO MIZUTANI	001560-350	2480

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BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
IBRAHIM, MEDINA AHMED	

ART UNIT	PAPER NUMBER
1638	21

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/147,955	MIZUTANI ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11 and 16-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,9-11,16,17,19-21 and 23-41* is/are rejected.

7)☐ Claim(s) *4,18,22 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/03 has been entered.

Claims 1-7, 9-11 and 16-42 are pending and are under consideration.

Withdrawn rejections

The 112, 1st paragraph rejections to claims 4, 18, 22, and 42 have been withdrawn in view of the sequence homology between the disclosed sequence as set forth in the table on page 9 of the response filed 01/03/03.

New Matter

Claims 25-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claims 25-39 recite an isolated DNA derived from "*Anthophyta* or *Mangnoliophyta*", *"Dictyledonopsida*" and "phyogenetic relationship of glucosyltransferase". However, support for these limitations cannot be found in the specification or in the claims as originally filed. Therefore, the limitation is considered to

be a new matter. Applicant is requested to point to support for the limitation in the originally filed specification or to delete the New Matter in response to this rejection. The embodiments deleted from original claims 20-22 are insufficient to provide support for the limitations "*Anthophyta* or *Mangnoliophyta*", *"Dictyledonopsida*" and "phyogenetic relationship of glucosyltransferase".

Claim Objections

At claims 1-5 and 25-39"A" should be changed to ---The--- because it refers to a previous claim.

At claims 6, 10, and 16-19, "a DNA" should be changed to ---the DNA--- because it refers to a previous claim.

At claim 7, "a vector" should be changed to ---the vector--- because it refers to a previous claim.

At claim 9, "a host cell" should be changed to ---the host cell--- because it refers to a previous claim.

At claims 21-22 and 41-42, "An" should be changed to ---The--- because it refers to a previous claim.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-39 are indefinite because what is intended by "phyogenetic relationship of glucosyltransferase" is unknown. The phrase is neither defined in the specification nor that it is an art recognized phrase, and hence it is not known what is encompassed by the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-7, 9-11, 16-17, 19-21 and 23-41 are rejected under 35 U.S.C. 112, first paragraph because the specification is enabling for claims limited to the isolated nucleic acid molecules encoding SEQ ID NO: 2, 4, 6, 8 or 12, vectors and transgenic plant cells and plants comprising said nucleic acid molecules and a method of transforming a host cell/plant with said vector. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in previous Office actions. Applicant's arguments filed 01/03/03 have been considered but not all are persuasive.

Applicant's argument is basically the following: 1) sequences disclosed in the specification share high degree of homology, and therefore can be used as probes and primers to obtain additional DNA sequences encoding proteins having flavonoid or anthocyanin 5GT activity, without undue experimentation.

This argument is not persuasive for the following reasons: firstly, claim 1 is so broad that it encompasses numerous DNAs of plant and non-plant origin. Applicant has provided no evidence to support the conclusion that the sequences disclosed in the specification can be used to identify any and all DNAs from any source encoding a protein having flavonoid. Claim 2 is so broad in that it encompasses numerous DNAs encoding proteins having multiple amino acid deletions and/or additions that retain flavonoid 5GT activity. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a proteins' s amino acid sequence and obtain the desired 5GT activity requires specific guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification. However, the instant specification lacks such guidance. Secondly, one skilled in the art would not expect that the majority of DNAs encoding a protein having as low as 30% sequence identity with SEQ ID NO: 2, 4, 6, 8 or 12 would retain 5GT activity because the disclosed sequences share from 49% to 69% identity. Thirdly, the hybridization conditions as set forth in claim 5 may not yield functional DNAs encoding the desired protein because of the moderate stringency and no wash time is specified. Fourthly, the disclosed sequences are all anthocyanins from related plant species, namely, *Perilla frutescene, Verbena and Petunia hybrid, and Torenia hybrira*. In addition, it is not known how many flavonoid encoding DNAs a single plant species can contain, and if these DNAs are developmentally or tissue specific.

Therefore, for the reasons discussed above and in the last Office actions, the scope of the claims is not commensurate with the enabling disclosure (In *re Wands*

858F.2d *731, 8 USPQ2d 1400 (Fed. Cir. 1988).* See also, *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 CCPA 1970.

Written Description

Claims 1-3, 5-7, 9-11, 16-17, 19-21, 23-24, 39-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in previous Office actions. Applicant's arguments filed 01/03/03 have been considered but are not persuasive with respect to the instantly rejected claims.

Applicant's arguments are basically the following: 1) 5 GT sequences from 4 plant species have been described in the specification, and 2) the specification teaches how to obtain and screen DNA falling within the scope of the claims.

These arguments are not persuasive because the disclosed sequences are from four related plant species, and the claims encompass various sequences from plants and non-plant origins.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian cDNA. Referring to the written description requirement as set forth in Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), the court stated:

> An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention... Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention

and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity...Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes...does not necessarily describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of any and all DNAs encoding a protein having flavonoid 5GT or anthocynanin 5GT activity. There is known correlation between the structure and function of a DNA sequence encoding a protein having flavonoid or anthocynanin 5GT activity. A substantial variation in structures are expected among DNAs encoding a protein having as low as 30% sequence identity, or DNAs encoding a protein modified by multiple deletions and/or additions. Because of the less stringency and no wash time specified, one skilled in the art would not expect that DNAs of claim 5 would be structurally and functionally related to SEQ ID NO: 1, 3, 5, 7 or 11. Consequently, the specification has not provided an adequate description for expression vectors, host cells, and plants comprising said DNA, and a method that employs said DNA.

Therefore, for the reasons discussed above and in the last Office actions, the claimed invention does not meet the current written description requirements. See, also, the Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 5-7, 9-11, 16-21, 23-26, 29-31, 34-36, 39-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Brugliera et al (US 5, 859, 334, filed 1995) in light of Jonsson et al (Planta, vol 160, pp. 341-347 (1984), Applicant's IDS). This rejection is repeated for the reasons of record as set forth in previous Office actions. Applicant's arguments filed 01/03/03 have been considered but are not persuasive.

The claims are drawn to an isolated DNA encoding a protein having flavonoid or anthocyanin 5GT activity, and said DNA hybridizes to all or portion of SEQ ID NO: 1, 3, 5, 7, or 11, or said DNA encodes a protein having one or more deletions and/or additions relative to SEQ ID NO: 2, 4, 6, 8, or 10 and having flavonoid 5GT activity.

Brugliera et al teach an isolated DNA encoding a protein having flavonoid 5GT activity (columns 2-3). In column 10, line 49, Brugliera cites Jonsson et al who teaches isolated and purified 5GT from Petunia. The cited reference also teaches vectors for transformation of plants/cells, transgenic plant phenotype analysis, and extraction of pigments (Examples 10-14). Applicant has not provided specific structural characteristics such as sequences that distinguish the claimed 5GT DNA from those of the prior art.

Applicant argues that none of the cited teaches sequence information for 5GT. Applicant further argues that this rejection appears to be contrary to the enablement rejection set forth above (response page 13).

These arguments are not persuasive because the rejected claims are not directed to specific sequences of 5GT (specific % sequence identity or specific stringency conditions). The rejected claims are drawn to an isolated DNA encoding a protein having flavonoid or anthocyanin 5GT activity, an isolated DNA that hybridizes to a portion of SEQ ID NO: 1, 3, 5, 7, or 11 under less stringent conditions with no wash time specified, and a DNA that encodes a protein having one or more deletions and/or additions relative to SEQ ID NO: 2, 4, 6, 8, or 10, each having 5GT activity. Applicant has provided no clear and convincing evidence as to why these DNAs are not anticipated by the cited reference. This rejection is proper and is not contrary to the enablement rejection above. The rejection is maintained.

Remarks

7. Claims 3-4, 18, 27-28, 22, 32-33, 37-38 and 42 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated DNA having at least 50% sequence identity to SEQ ID NO: 1, 3, 5, 7, or 11, or DNA encoding a protein having at least 30% or 50% sequence identity to SEQ ID NO: 2, 4, 6, 8, or 10 that retains 5GT activity.

Claims 4, 18, 22 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina a. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Thursday from 9:00AM to 6:00 P.M. and every other Friday from 9:00-5:30P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 and (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications. Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

12/24/03
Mai